UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,193	09/29/2005	Genevieve Andre-Fontaine	033339/292053	9098
826 7590 11/17/2008 ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000			EXAMINER	
			RUSSEL, JEFFREY E	
	NC 28280-4000	E 4000	ART UNIT	PAPER NUMBER
			1654	
			MAIL DATE	DELIVERY MODE
			11/17/2008	PAPER

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1654

1. The proposed amendments to the claims filed November 4, 2008 will not be entered because they are not in compliance with 37 CFR 1.121(c)(2). The proposed amendments do not accurately mark all changes to be made to the claims. At proposed claim 1, line 5, a semicolon has been inserted after "Lys" without underlining. At proposed claim 1, line 9, a comma is missing from after the word "acids". At proposed claim 21, line 2, a comma has been deleted from after "claim 1" without the comma being marked with strikethrough.

- 2. The proposed amendments filed November 4, 2008, had they been entered, would have overcome the rejection under 35 U.S.C. 112, first paragraph, and the claim objections set forth in sections 3 and 5 of the final Office action mailed July 9, 2008.
- 3. The proposed new claim limitation reciting a peptide consisting of the sequence SEQ ID NO:1 plus an additional N-terminal cysteine residue is a new claim limitation which would require further consideration and/or search.

The proposed new claim limitations reciting methods of making the peptide coupled to a carrier protein are new claim limitations which would require further consideration and/or search. Further, the proposed new claim limitations raise issues under 35 U.S.C. 112, second paragraph, for lack of antecedent basis for the phrase "the DNA coding sequence" (both occurrences), and because "the DNA coding sequence" implies that there is only a single DNA coding sequence for the peptide and for the carrier protein, which is factually incorrect. Because of redundancy in genetic coding of amino acids, there will always be multiple possible DNA coding sequences for a given peptide or protein. In any event, it should be noted that the proposed claim language does not distinguish over the full length PPL protein taught by the WO

Art Unit: 1654

Patent Application 01/59123. Full length proteins are capable of being synthesized either chemically or recombinantly.

- 4. The proposed claim language "compound... comprises a peptide" does not appear to resolve the issues raised in the rejection under 35 U.S.C. 112, second paragraph (see section 4 of the final Office action) and in the prior art rejections, at least not in the manner intended by Applicants. Regardless of Applicants' arguments, because of the explicit use of "comprises", the proposed claim language clearly would embrace the full length PPL protein taught by the WO Patent Application '123. The transitional term "comprises" does not exclude additional unrecited elements (see MPEP 2111.03), and therefore does not exclude the additional unrecited amino acids which are present in full length PPL protein. Again, if the claim language should be interpreted as permitting the covalent attachment of a carrier protein to a peptide consisting of SEQ ID NO:1, the claim language will permit the covalent attachment of other amino acids, i.e. the remaining portions of full length PPL protein, to the peptide.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Application/Control Number: 10/533,193 Page 4

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/ Primary Examiner, Art Unit 1654

JRussel November 18, 2008